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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/637,190	08/08/2003	Curt Dale Haffner	PU3616US2	5880

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EXAMINER	
ANDERSON, REBECCA L	
ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/637,190	HAFFNER ET AL.	
	Examiner	Art Unit	
	Rebecca L Anderson	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16 and 36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 16 and 36 are currently pending in the instant application and are rejected.

Response to Amendment

Applicants amendment to claim 16 to include the structure of GW4064 has overcome the 35 USC 112 2nd paragraph rejection of this claim for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Response to Arguments

Applicant's arguments filed 19 July 2004 in regards to the 35 USC 112 1st paragraph rejection of claims 16 and 36 have been fully considered but they are not persuasive. Applicant argues that the claimed invention is a method of lowering serum triglycerides and that while the it is accepted that there must be a reasonable correlation between the scope of what is claimed and the scope of enablement proved by the specification to the person of ordinary skill in the art that the present patentability analysis has improperly imported limitations from the specification (treatment of disease) into the claims. These arguments are not found persuasive, because, the test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the specification couples with information known in the art without undue experimentation and in making the determination of enablement, the examiner shall consider the original disclosure and all evidence in the record. Therefore, the examiner has referred to applicants instant specification in order to make

a determination of whether one reasonably skilled in the art could use the invention from the disclosure and the information known in the art. Applicants disclosure provides the use or utility of lowering serum triglycerides is for the treatment of any disease associated with the modulation of lipid levels. Appropriately, the Examiner has concluded that the instant disclosure coupled with the information known in the art only provides enablement for the lowering of serum triglycerides for the treatment of artherosclerosis and not for the treatment of any disease or disorder that applicant considers associated with the modulation of lipid levels. Therefore, the rejection of claims 16 and 36 under 35 USC 112 1st paragraph is maintained.

Maintained Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16 and 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for the method of lowering serum triglycerides ina mammal for the treatment of atherosclerosis does not reasonably provide enablement for the treatment of all disease mediated by modified lipid levels. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a

disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The nature of the invention

The nature of the invention in claims 16 and 36 is the lowering of serum triglycerides in a mammal by administering the compound of claim 36. The claim fails to state the benefit of lowering serum triglycerides in a mammal {e.g., what disease/disorder is being treated or prevented?} However, the specification states that the lowering of serum triglycerides in a mammal is for the treatment of any disease associated with modified lipid levels, pages 8 and 9.

The state of the prior art

The state of the prior art is that farnesoid X receptor is a bile acid-activated transcription factor that is a member of the nuclear hormone receptor superfamily. The farnesoid X receptor functions as a bile acid sensor coordinating choleterol metabolism, lipid homeostasis and absorption of dietary fats and vitamins.

The predictability or lack thereof in the art

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to therapeutic effects of diseases characterized by modified lipid levels, whether the disease included by this claim are affected by a compound which lowers serum triglycerides would affect the possible treatment of any disease.

Hence, one of skill in the art is unable to fully predict possible results from the administration of the compound of formula (I) due to the unpredictability of the role of serum triglycerides and the unpredictability as to what diseases are encompassed by the instant claims. The nature of the pharmaceutical arts is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities and which diseases would be affected by this activity. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The amount of direction or guidance present

The direction present in the instant specification is the binding assays on pages 11-18.

The presence or absence of working examples

There are no working examples in the instant specification for the treatment of any disease applicant considers characterized by modified lipid levels. The compounds which are disclosed in the specification have no pharmacological data regarding the treatment of any of the diseases and fails to provide working examples as to how the diseases are correlated the lowering of serum triglycerides

The breadth of the claims

The breadth of the claims encompassesthe lowering of serum triglycerides for the treatment of any disease characterized by lowered serum triglycerides.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what diseases characterized by the modification of lipid levels would benefit from lowered serum triglycerides and would furthermore then have to determine what compounds of the elected invention would provide treatment of what, if any, disease.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus the specification fails to provide sufficient support for the broad use of the compound of the formula (I) for the method of lowering serum triglycerides for the treatment of any disease characterized by a modification of lipid levels. As a result necessitating one of skill to perform an exhaustive search in order to practice the claimed invention.

Genentech Inc.v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vaque intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors and in re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation with no assurance of success. This rejection can be overcome by amending the claims to include only method of lowering serum triglycerides for the treatment of atherosclerosis

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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